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February 17, 2006

MAIL STOP PCT

Commissioner for Patents P.O. BOX 1450 Alexandria, VA 22313-1450

PCT/JP2004/012136 -filed August 18, 2004

Re:

Application of Satoko YAMAHIRA, Masamichi TOBA, and Hiroshi

OKAMATSU

LACTIC ACID BACTERIA CAPABLE OF STIMULATING MUCOSAL

IMMUNITY

Assignee: OTSUKA PHARMACEUTICAL CO., LTD.

Our Ref: 093246

Dear Sir:

1

The following documents are submitted herewith in connection with the above application for the purpose of entering the National stage under 35 U.S.C. §371 and in accordance with the Patent Cooperation Treaty:

- ☑ a copy of the executed Declaration and Power of Attorney.
- ✓ an verified English translation of the International Application.
- ☑ Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.
- \square two (2) sheets of drawings (Figs. 1-2).
- ☑ a copy of the executed Assignment and PTO 1595 form.
- ☑ Information Disclosure Statement and a copy of the ISR.
- ☑ Notification Concerning Submission or Transmittal of Priority Document.
- ☑ a PTO/SB/08 A & B (modified) listing the ISR references.
- ☑ a Preliminary Amendment.

In addition to the documents submitted herewith, it is assumed that copies of the International Application, the International Search Report and cited references, the International Preliminary Examination Report, and any Articles 19 and 34 amendments as required by §371(c) will be supplied directly by the International Bureau, but if further copies are needed, the undersigned will undertake to provide them upon request.

It is expressly requested that the national stage of processing be commenced immediately in accordance with 35 U.S.C. § 371(f).



IAP20 Rec'd PCT/PTO 1 7 FEB 2006

Commissioner for Patents

Appln. No.: National Stage of PCT/JP2004/012136

Attorney Docket No. Q93246

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The Government filing fee, after entry of Preliminary Amendment, is calculated as follows:

Total claims	10 -	20	=		X	\$50.00	=	\$.00
Independent claims	1 -	3	=		x	\$200.00	= -	\$.00
Base Fee							_	\$300.00
Search Fee*							_	\$400.00
Examination Fee*							_	\$200.00
							_	
TOTAL FILING FEE					\$900.00			
Recordation of Assignment						\$ 40.00		
TOTAL FEE							_	940 00

^{*} The international search fee for all claims was not paid to the USPTO, as the ISA, but the ISR is being submitted herewith.

Checks for the statutory filing fee of \$900.00 and Assignment recordation fee of \$40.00 are attached. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this transmittal letter is attached.

Priority is claimed from:

Country

Application No

Filing Date

Japan

2003-297570

August 21, 2003

Respectfully submitted,

Gordon Kit

(Registration No. 30,764)

SUGHRUE MION, PLLC

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WASHINGTON OFFICE 23373

CUSTOMER NUMBER

Date: February 17, 2006

VERIFICATION OF A TRANSLATION 1AP20 ROSS (1011) (17 7 12 2006)

I, the below named translator, hereby declare that:

My name and post office address are as stated below:

That I am knowledgeable in the English language and in the language in which the below identified international application was filed, and that I believe the English translation of the international application No. <u>PCT/JP2004/012136</u> is a true and complete translation of the above identified international application as filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilfulfalse statements may jeopardize the validity of the application or any patent issued thereon.

	Date
	February 3, 2006
Full name of the trans	slator Yumi KUJIME
Signature of the trans	slator Juni Kujime
Post Office Address _F	Kitahama TNK Building 7-1, Dosho-machi
_1	-chome, Chuo-ku, Osaka-shi, Osaka 541-0045
J	apan

TRANSLATION

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS

FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the

INTERNATIONAL DEPOSITARY AUTHORITY identified

at the bottom of this page.

Depositor : Name

: OTSUKA PHARMACEUTICAL CO., LTD.

Tatsuo HIGUCHI, Esq., President

Address: 9, Kandatsukasa-cho 2-chome

Chiyoda-ku, Tokyo-to 101-8535, Japan

IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR

Accession number:

FERM BP-10065

Lactobacillus ONRIC b0239

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

a scientific description

a proposed taxonomic designation

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on (original deposition date.)

IV. RECEIPT OF REQUEST OF TRANSFER

This International Depositary Authority received the microorganism identified under I above on August 6, 2003 (national deposition date).

Said microorganism was transferred from FERM P-19470 deposited on August 6, 2003.

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name

International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology

Dr. Masakazu YAMAOKA, Director (seal)

Address : AIST Tsukuba Central 6, 1-1, Higashi 1-chome,

Tsukuba-shi, Ibaraki-ken 305-8566, Japan

July 12, 2004